U.S. Department of Justice

United States Attorney
Southern District of New York

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January 14, 2022

BY ECF/EMAIL
Honorable Mary Kay Vyskocil
United States District Judge
Southern District of New York
500 Pearl Street
New York, New York 10007

RE: *United States* v. *Seth Fishman and Lisa Giannelli,* S6 20 Cr. 160 (MKV)

Dear Judge Vyskocil:

The Government writes in further support of its motion *in limine* to admit information related to the investigation by the Delaware Division of Professional Responsibility ("DPR"), and to address several other topics raised at the January 13, 2022 conference.

First, the death of a particular horse, Louisville, that had allegedly received an injection of Pentosan from a bottle that Lisa Giannelli had sold,[1] is more probative than prejudicial given the findings the jury must make regarding: (1) whether these and similar drugs were adulterated, *i.e.*, unsafe, *see* 21 U.S.C. § 351(a)(5) (A drug is deemed adulterated "if it is a new animal drug which is unsafe" within the meaning of the FDCA, 21 U.S.C. § 351(a)(5)); and (2) the defendants' state of mind in distributing injectable drugs to a lay person without a prescription or supervision.

A drug is considered "unsafe" if it does not have a "general reputation in the scientific community" as "safe and effective for its intended uses," *see United States v. Undetermined Quantities of Various Articles of Drug . . . Equidantin Nitrofurantoin Suspension ...*, 675 F.2d 994, 999–1000 (8th Cir. 1982) (citation and internal quotation marks omitted). To clarify, the Government does not intend to present evidence suggesting that the horse died as the result of an impurity in the batch of Pentosan Giannelli sold.[2] Even assuming as correct the defense's argument

[1] The Government notes that, although the Delaware complaint alleges that Giannelli sold the drug, the Government's position is that the horse in question was *not* under Fishman's care. Fishman's veterinary license was merely the pretext for Giannelli's illegal sales.

[2] The complainant in the Complaint writes the following regarding the horse's death:

> Talked to the grooms in the barn….Gave the animal pentosan gold injectable 12 ml iv slowly over the course of around 1-2 minutes, felt confident in the vein. Went to put on his blanket and animal *started to hyperventilate and appear unsteady,*

that the horse died as a result of "inter-arterial injection of the product administered," Defs. Opp'n at 7 (ECF No. 599), this supposed cause of death necessarily bears upon the safety and efficacy of defendants' distribution of an IV drug to lay people with no valid medical purpose, with no valid prescription, and with no supervision. "All evidence introduced against a defendant, if material to an issue in the case, tends to prove guilt, but is not necessarily prejudicial in any sense that matters to the rules of evidence." *United States v. Figueroa*, 618 F.2d 934, 943 (2d Cir. 1980) (citing *United States v. Briggs*, 457 F.2d 908, 911 (2d Cir.), *cert. denied*, 409 U.S. 986 (1972)). "Evidence is prejudicial only when it tends to have some adverse effect upon a defendant beyond tending to prove the fact or issue that justified its admission into evidence." *Id.* Admitting the horse's death is squarely within the scope of the necessary showing regarding the safety and efficacy of the drugs the defendants distributed.

Adverse events linked to the distribution of Pentosan specifically, and intravenous drugs distributed by the defendants generally, will necessarily bear upon whether the drugs distributed by Fishman and Giannelli—including Pentosan and several other drugs manufactured by Fishman which likewise require IV administration—are safe and effective. Such evidence is not unduly prejudicial, given that considering the safety and efficacy of the drugs the defendants sold is among the inquiries relevant to the elements of the charged offense. It is highly probative to this inquiry to present evidence that mis-administration of IV drugs can lead to death, underscoring why certain drugs require a prescription, the supervision of a licensed medical professional, and/or are otherwise not generally recognized as safe and effective among qualified professionals.

The Government anticipates testimony from Dr. Jean Bowman explaining that drugs intended to be administered intravenously are, as a matter of course, designated prescription drugs administered by a licensed medical professional pursuant to valid prescription precisely because of the difficulties in properly finding a vein, and the risks of incorrectly administering such a medication. Dr. Bowman is further anticipated to testify that the risks associated with the intended method of administration of a drug bear upon whether a drug will require a prescription, or whether it may be sold "over the counter." The Government should be permitted to present evidence regarding the full scope of ramifications that follow from administering an IV drug with no valid prescription, and *not* under the supervision of a veterinarian.

The horse's death further bears upon the state of mind of the defendants, with respect to: (1) their continued sales of Pentosan, two versions of which were included on an inventory list that Giannelli distributed to customers as of at least 2018, and which were saved to her computer; and (2) Fishman's other "new animal drugs," many of which required IV injection, yet were distributed without a prescription to lay people, and not administered by Fishman himself. Fishman was

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> *they gave him a short of dexamethasone and shortly after the horse went down to left lateral recumbency,* took some agonal breaths and died.

The Government respectfully posits that redaction of the italicized portions of the Complaint further lessens the prejudicial effect of introducing the horse's death. The Government's intent is not to belabor the suffering of the animal, but to convey the full spectrum of risks associated with distributing IV drugs to laypeople, in aiding the jury's determination of whether such drugs are adulterated.

apprised on multiple occasions of the risks of Pentosan, with the Delaware death being one in a string of warning signs that his practices were dangerous. For example, on a March 31, 2019 call between Fishman and one of his overseas partners who purchased and distributed Fishman-sourced drugs, Fishman was again informed that "Pentosan Gold" distributed by this individual caused "3 horses [to] die[] by 3 months, 3 months, died." *See* GX 122A-T. Fishman responded by affirmatively acknowledging the risks of administering an injectable: "you gotta be very careful these very high concentrated medical devices, they all can be problematic especially if guys are rushing the injection . . . ." *Id.* Notwithstanding these risks, Giannelli and Fishman continued to market and sell drugs requiring IV injection to lay people, including two versions of Pentosan. *See* GX 709 at 5. Finally, the *degree* of danger inherent in the sale of the Fishman products corresponds directly to Fishman and Giannelli's efforts to hide their activity from regulators. Knowing full well that they were selling unsafe, ineffective drugs (*i.e.*, "adulterated" drugs), the two went to great lengths to screen clients for potential informants, disguise their illegality behind false prescriptions, and to lie to the very regulators investigating the death of Louisville.

Consequently, and in light of the issues germane to this case and the Government's burden at trial, inclusion of the fact that a horse died after receiving an IV medication that Giannelli sold and that both defendants offered for sale has far more probative value than any prejudicial effect arising from the very nature of the charged offense.

Second, with respect to the outcome of the Delaware Division of Professional Responsibility's investigation, the Government and defense counsel have conferred and agreed to a factual stipulation that the parties anticipate will be introduced at trial.

Third, after conferral with defense counsel, the Government has received no objection following a conference and circulation of the proposal below. Consequently, the Government respectfully proposes the following summary of the case to provide to the jury in advance of voir dire:

This is a criminal case. The defendants on trial, SETH FISHMAN and LISA GIANNELLI, have been charged with the commission of federal crimes in an Indictment filed by a Grand Jury sitting in this District.

The Indictment is not evidence itself. It simply contains the charges that the Government is required to prove to the satisfaction of the trial jury beyond a reasonable doubt. Those of you selected to sit on this jury will receive a detailed explanation of the charges at the conclusion of the case, but I would like to give you a brief summary of the charges so that we can determine whether there is anything about the charges that would make it impossible or difficult for you to sit as a fair and impartial juror.

The Indictment contains two counts or "charges." Specifically, Count One of the Indictment charges that, from at least in or about 2016 through at least in or about March 2020, SETH FISHMAN, conspired with others—that is, agreed with others—to violate the federal criminal law prohibiting what is known as drug adulteration or misbranding with the intent to defraud or mislead. Specifically, FISHMAN is charged with agreeing with others to distribute adulterated and misbranded performance-enhancing drugs, also referred to as "PEDs," which were intended

to enhance the performance of thoroughbred racehorses competing in the United States and overseas.

Count Two of the Indictment charges that, from at least in or about 2002 through at least in or about March 2020, SETH FISHMAN and LISA GIANNELLI agreed, together and with others, to sell adulterated and misbranded PEDs which were intended to enhance the performance of standardbred and thoroughbred racehorses.

Respectfully submitted,

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